K002057

OCT - 4 2000

BIOMET INC

CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Proprietary Name: Brooker Tibia Nails

Classification Name and Reference: Rod, fixation, intramedullary and accessories (21 CFR 888.3020)

Intended Use: The Brooker Tibial Nail is a single use device intended for fixation of fractures in the tibia.

Device Description: The Brooker tibial nail is a stainless steel rod with a tubular square cross-section. Nails are 10mm in diameter and come in 1cm incremental lengths of 28 to 42cm. Proximally two screw holes allow placement of cross screws at a 45° angle to the nail shaft. Five-millimeter cortical and cancellous screws in a variety of lengths are used for proximal fixation. The proximal end is threaded, allowing for attachment to an insertion tool. This provides the surgeon with a stable, easily controlled unit during insertion. Prior to wound closure, a proximal capping screw is placed in the end of the nail to prevent soft tissue and bone ingrowth.

Distal fins provide additional stability. The device comes pre-assembled with a central rod used for deployment of distal fixation fins. Once the nail is in place, a light mallet tap on the deploying rod deploys the fins. The fins spread out through slots in the nail, providing rotation stability without the use of distal screws that may disturb knee mechanism. Unlike nails which employ distal screws, this mechanism also allows for complete implantation through a single incision, resulting in less operating time and improved cosmetic results.

Substantial Equivalence: The Brooker Tibial Nail is substantially equivalent to the following devices: Uniflex Tibial Nail (Biomet, Inc), and Küntscher Tibial Nails (OEC/Biomet, Inc.).

Potential Risks: The potential risks associated with this device are the same as with any other fixation device. These include but are not limited to:1) Delayed or nonunion that may lead to breakage of the implant; 2) Bending, fracture or migration of the implant; 3) Loosening or migration of the implant; 4) Metal sensitivity or allergic reaction to a foreign body; 5) Limb shortening due to compression of the fracture or bone resorption; 6) Decrease in bone density due to stress shielding; 7) Pain, discomfort or abnormal sensations due to the presence of the device; 8) Nerve damage due to surgical trauma; 9) Nercrosis of bone; 10) Postoperative bone fracture and pain; 11) Inadequate healing; 12) Infection; 13) Hematoma

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2000

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K002057
Trade Name: Brooker Tibia Nails
Regulatory Class: II
Product Code: HSB
Dated: July 6, 2000
Received: July 6, 2000

Dear Ms. Beres:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Brooker Tibial Nail

Indications For Use:

The Brooker Tibial Nail is a single use device intended for fixation of fractures of the tibia

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002057

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)